DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004M–0024, 2004M–0147, 2004M–0145, 2004M–0031, 2004M–0022, 2004M–0012, 2004M–0064, 2004M–0116, 2004M–0084, 2004M–0090, 2004M–0134]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2004, through March 31, 2004. There were no denial actions during

this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2004, THROUGH MARCH 31, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P970020(S40)/2004M–0024	Guidant Corp.	ACS MULTI–LINK RX/OTW DUET CORONARY STENT SYSTEMS	August 6, 2002
P890064(S9)/2004M–0147	Digene Corp.	DIGENE HYBRID CAPTURE 2 (HC2) HIGH-RISK HPV DNA TEST	March 31, 2003
P020006/2004M–0145	Enteric Medical Technologies, Inc.	ENTERYX PROCEDURE KIT	April 22, 2003
P020031/2004M–0031	Microsulis Corp.	MICROSULIS MICROWAVE ENDOMETRIAL ABLATION	September 23, 2003
P010059/2004M–0022	Morcher GMBH	MORCHER CAPSULAR TENSION RING, TYPES 14, 14A, and 14C	October 23, 2003
P030002/2004M–0012	Eyeonics, Inc.	CRYSTALENS MODEL AT–45 ACCOMMODATING POSTERIOR CHAMBER INTRAOCULAR LENS	November 14, 2003
P030005/2004M–0064	Guidant Corp.	CONTAK RENEWAL MODELS H125 and H120 WITH MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	January 26, 2004
P030006/2004M–0116	Celsion Corp.	PROLIEVE THERMODILATION SYSTEM	February 19, 2004
H030004/2004M–0084	Menssana Research, Inc.	HEARTSBREATH	February 24, 2004
H030003/2004M–0090	MicroMed Technology, Inc.	DEBAKEY VAD CHILD LEFT VENTRICULAR ASSIST SYSTEM	February 25, 2004
P010018(S5)/2004M–0134	Refractec, Inc.	VIEWPOINT CK SYSTEM	March 16, 2004

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: June 7, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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